Patent Application Attorney Docket No. PC10927A United States Patent Application No. 09/899,322

homopiperidinyl group classified in class 540 and several subclasses.

Group II. Claims 76-104 and 119-152 drawn to compounds, and composition wherein R⁵ is morpholinyl group classified in class 544 and several subclasses.

Group III. Claims 76-104 and 119-152 drawn to compounds, and compositions wherein R⁵ is piperidinyl group classified in class 546 and several subclasses.

Group IV. Claims 76-104 and 119-152 drawn to compounds, and composition wherein R⁵ is pyrrolidinyl group classified in class 548 and several subclasses.

Group V. Claims 105-106, drawn to a process of preparing compounds, variously classified in classes 540, 544, 546 and 548, and several subclasses.

Group VI. Claims 112-113, drawn to a process of preparing compounds, variously classified in classes 540, 544, 546 and 548, and several subclasses.

Group VII. Claims 114-117, drawn to a process of preparing compounds, variously classified in classes 540, 544, 546 and 548, and several subclasses.

Applicants hereby elect with traverse to prosecute the claims of Group III in this application. Applicants respectfully submit that the Examiner has arbitrarily restricted the subject application and the restriction requirement is not in compliance with US PTO rules and guidelines. Applicants respectfully request that the Examiner reconsider the appropriateness of the issued restriction requirement and withdraw it for the following reasons. Additionally, if the Examiner after consideration of applicants' response still believes the application should be restricted they respectfully request that such a restriction requirement be issued in compliance with the US PTO rules and guidelines.

Applicants note that the Examiner has divided the subject application into seven groups. The Examiner has not however included claims 107-111 in any of the seven groups

of the restriction requirement. Applicants assume that this was an oversight by the Examiner and respectfully request clarification concerning claims 107-111 in the Examiner's next action.

The Examiner has apparently based his restriction of claims 76-104 and 119-152 of the subject application based upon a non-core substituent, R⁵. The claimed invention is directed to derivatives having a <u>pyrazole core</u> and methods of making the aforementioned compounds. Applicants' note that that pyrazole core has four substitutents attached R¹, R², R³ and R⁴. The R⁵ substituent is contained within the definitions of substituents attached to the pyrazole core. The Examiner has chosen homopiperidinyl, homopiperazinyl, morpholinyl, piperidinyl and pyrrolidinyl group from the Markush definition of R⁵ shown below.

"each R5 is independently either H, C1-C6 alkyl, C3-C7 cycloalkyl, fluoro-(C₁-C₆)-alkyl, phenyl or benzyl, or, when two such groups are attached to the same nitrogen atom, those two groups taken together with the nitrogen atom to which they are attached represent azetidinyl, pyrrolidinyl, piperidinyl, homopiperidinyl, piperazinyl, homopiperazinyl or morpholinyl, said azetidinyl, pyrrolidinyl, piperidinyl, homopiperidinyl, piperazinyl, homopiperazinyl and morpholinyl being optionally substituted by C₁-C₆ alkyl or C₃-C₇ cycloalkyl and said piperazinyl and homopiperazinyl being optionally substituted on the nitrogen atom not taken together with the two R⁵ groups to form the ring by -COR⁷ or -SO₂R⁷; (emphasis added)"

The Examiner has provided no explanation as to why he has chosen to arbitrarily restrict the subject application in such a manner. In order to restrict a patent application the Examiner has the burden of satisfying the the following criteria: (i) he must show that the application claims independent or distinct inventions as required by both 35 U.S.C. § 121 and the PTO rules; and (ii) the Examiner must show that examining all claimed inventions in a single application would constitute a serious burden. M.P.E.P. §803. Applicants respectfully submit that it is not an undue burden for the Examiner to examine all of the inventions listed above since they will all have a pyrazole core in common.

Accordingly, any search for pyrazole compounds with variable substitutents will necessarily turn up art for each of the inventions identified by the Examiner.

With respect to Groups V-VII the Examiner has chosen to remain silent on the subject matter of these claims except to indicate that they are "drawn to a process of making compounds". The Examiner has apparently been able to identify a class for each of these inventions without informing applicants of the subject matter claimed in each group as required under patent office practice. See, M.P.E.P. §817. Applicants further note that the classes identified for the inventions of Groups V-VII are identical. Applicants respectfully submit that since the inventions are within the same classes any resulting search will identify art for each of the inventions of Groups V-VII.

Applicants further submit that even if the Examiner continues to maintain his restriction of the subject application that it is improper in the present form. The Examiner has failed to classify each of the inventions into a class and subclasse(s). In MPEP §817 the outline of a letter for restriction requirement between distinct inventions is provided. The letter notes that the Examiner should as part of the restriction requirement letter "classify each group." Applicants respectfully submit that in each invention I-VII shown above and listed in the Examiner's November 23, 2001 restriction requirement no subclasses having been identified by the Examiner. The Examiner merely states that each of the claimed invention falls within "several subclasses". Applicants respectfully request that the Examiner provide a list of the "several subclassess" for each of the inventions listed. Furthermore, applicants also request that Examiner inform applicants why he classified each of the claimed inventions in the particular classes. Each of the classes identified for each of the inventions by the Examiner has the same descriptive title "organic compounds." Without the specification of the subclasses the Examiner's restriction of the subject application is meaningless. The Examiner has asserted that the inventions of Groups I-IV have acquired a separate status in the art and are distinct because they differ in structure. The Examiner concluded "to not restrict would impose a burden in the examination of the application." Applicants respectfully submit that the Examiner has merely conclude that a serious burden exist but has provided no reasons or evidence on the record to substantiate either a separate classification, separate status in

the art or a different field of search for the separate inventions. The Examiner has not met his burden of showing grounds for a restriction requirement.

Moreover, the Examiner has also failed to provide a clear record for applicants to appeal the Examiner's restriction requirement. As noted in MPEP 706.07 "[t]he examiner should never lose sight of the fact that in every case the applicant is entitled to a full and fair hearing, and that a clear issue between the applicant and examiner should be developed, if possible, before appeal." Applicants respectfully submit that the Examiner has failed to provide adequate reasoning to support his classification of the subject application in to the inventions identified above.

Applicants also note that the Examiner's current restriction requirement will invariably result in an unlimited number of applications since applicants will be confronted with still more groups once the Examiner examines the elected subject matter and excludes from examination other subject matter falling outside the scope of the examined subject matter. Applicants further note that 37 C.F.R. §1.141(a) provides that an application can claim more than one distinct species, not to exceed a reasonable number, so long as the application also includes an allowable generic claim embracing the generic species. Applicants also note that restriction practice for Markush type claims under M.P.E.P. §803.02 states that if no prior art is found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. Accordingly, applicants respectfully request that the Examiner contact applicants' attorney for additional substituents from the R⁵ definition to search if the elected subject matter inclusive of the elected species is found to be allowable by the Examiner. However, applicants still maintain that the restriction requirement as written is improper and should be withdraw. Accordingly, applicants respectfully request that the Examiner examine all the claimed inventions in a single application since it would not constitute a serious burden.

Supplemental Information Disclosure Statement

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Pursuant to 37 C.F.R. §1.97(c) applicants herein make available to the U.S. Patent and Trademark Office a copy of PTO-FB-A820, which lists references cited by

applicants. Applicants also include copies of the each of the listed references for the Examiner's consideration.

The Examiner is requested to consider carefully the complete text of these references in connection with the examination of the above-identified application in accord with 37 C.F.R. § 1.104(a). It is believed the Examiner will concur with applicant's belief that the subject matter presently claimed is neither anticipated nor rendered obvious by the foregoing references.

It is requested that the references listed on the attached form PTO-FB-A820 be included in the "References Cited" portion of any patent issuing from this application (M.P.E.P. § 1302.12).

Acknowledgement of Priority Claims

Applicants also respectfully request that the Examiner in his next paper acknowledge applicants claim for domestic priority under 35 U.S.C. § 119(e) to provisional application no. 60/220,087, filed July 21, 2000 and foreign priority to U.K. patent application no. 0016787.4, filed July 7, 2000 in the Office Action Summary.

Petition for Extension of Time and Fees Due

Applicants' are submitting concurrently a Petition for a 2-Month Extension of Time for the subject application and authorizing the payment of a 2-month extension fee for the subject application. Applicants do not believe any additional fees are due in connection with the filing of this response to the November 23, 2001 Restriction Requirement. However, if any fee is due, the Examiner is authorized to charge the fee to applicants' Deposit Account No. 16-1445.

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Conclusion

Applicants respectfully request that the Examiner reconsider and withdraw the restriction requirement in the subject application for the reasons set forth above.

Applicants' undersigned attorney invites the Examiner of the subject application to contact him at the number listed below if the Examiner believes it will expedite the examination of the subject application or the Examiner has any questions with respect to the response filed herein. Applicants respectfully request prompt consideration of the pending claims and early allowance of the application.

Date: tehruay 6, 2000

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Respectfully submitted,

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